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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: David Stern and Ann-Marie Schmidt

Serial No.: 08/905,709 Group Art Unit: 1646

#23
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For : A METHOD TO PREVENT ACCELERATED ATHEROSCLEROSIS USING (sRAGE) SOLUBLE RECEPTOR FOR ADVANCED GLYCATION ENDPRODUCTS

1185 Avenue of the Americas
New York, New York 10036
March 4, 2002

Assistant Commissioner for Patents
Washington, DC 20231

SIR:

COMMUNICATION FURTHER TO AMENDMENT IN RESPONSE TO JUNE 29, 2001 OFFICE ACTION, CONFIRMATION OF SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT FILED ON MAY 11, 2001 AND PETITION FOR A THREE-MONTH EXTENSION OF TIME

This Communication is submitted further to a December 28, 2001 response to June 29, 2001 Office Action, Confirmation of Supplemental Information Disclosure Statement filed on May 11, 2001 and Petition for a Three-month Extension of Time filed with the United States Patent and Trademark Office in connection with the above-identified application.

Confirmation of the Information Disclosure Statement

Applicants would like to direct the Examiner's attention to the following documents allegedly not received by the patent office as

part of Request for Continued Prosecution Application, Supplemental Information Disclosure Statement and Preliminary Amendment filed on May 11, 2001, i.e. below listed references 2, 6, 7, 12, 17, 23 and 25, attached hereto as **Exhibits 1-7**. As confirmation of the supplemental information disclosure statement filed on May 11, 2001, and to ensure consideration of all references listed on Form PTO-1449 attached hereto as **Exhibit A**, applicants list below all 32 references. Please note that copies of below listed references 1, 3-5, 8-11, 13-16, 18-22, 24 and 26-32 were provided in the information disclosure statement filed on May 11, 2001. Applicants understand that all below listed references, i.e. 1-32, will now be considered by the patent office.

1. Brett, J, et al., (1993) Survey of the distribution of a newly-characterized receptor for AGEs in tissues. *Am. J. Pathol*, 143:1699-1712.

2. Connolly ES, Winfree CJ, Stern DM, Solomon RA, Pinsky DJ. (1996) Procedural and strain-related variables significantly affect outcome in a murine model of focal cerebral ischemia. *Neurosurg* 1996;38:523-532. **(Exhibit 1)**

3. Gibbons, G. H. and V. J. Dzau. (1996). Molecular therapies for vascular diseases. Science 272: 689-693.

4. Hori, et al. (1997) The Receptor for Advanced Glycation Endproducts: Implications for the Development of Diabetic Vascular Disease. Fundam. Clin. Cardiol. In: The Endothelium

in Clinical Practice. Chapter 11, pages 311-329.

5. Khoury, J., et al., (1994) Macrophages adhere to glucose-modified basement membrane collagen IV via their scavenger receptors. *J. Biol. Chem.*, 269:10197-10200.

6. Kindy, S. Mark and Rader, J. Daniel (1998) "Reduction in Amyloid A Amyloid Formation in Apolipoprotein-E-Deficient Mice," American Journal of Pathology 152:1387-1395. **(Exhibit 2)**

7. Marui, N., et al. (1993) VCAM-1 gene transcription and expression are regulated through an oxidant-sensitive mechanism in human vascular endothelial cells. *J. Clin. Invest.*, 92:1866-1874. **(Exhibit 3)**

8. Morser et al., U.S. Patent No. 5,864,018, filing date April 16, 1996.

9. Morser et al. PCT International Application No. PCT/EP97/01834, filed April 11, 1997, published October 23, 1997; Publication No. WO 97/39125, Antibodies Against the Advanced Glycation Endproduct Receptor and Uses Thereof.

10. Morser et al. PCT International Application No. PCT/EP97/01832, filed 11 April 1997, published October 23, 1997, Publication No. WO 97/39121, Advanced Glycation Endproduct Receptor Peptides and Uses Thereof.

11. Nakamura, Y. et al. (1993) Immunohistochemical localization of advanced glycosylation endproducts in coronary atheroma and cardiac tissue in diabetes mellitus. Am. J. Pathol. 143(6):1649-1656.

12. Nakashima Y, Plump A, Raines E, Breslow J, Ross R. (1994) ApoE-deficient mice develop lesions of all phases of atherosclerosis throughout the arterial tree. *Arterioscler Thromb* 1994;141:133-140. **(Exhibit 4)**

13. Neeper, M., et al. (1992). Cloning and expression of a cell surface receptor for advanced glycosylation end products of proteins. J. Biol. Chem. 267: 14998-15004.

14. Palinski, W. et al. (1995) Immunological evidence for the presence of advanced glycation end products in atherosclerotic lesions of euglycemic rabbits. *Arterioscl. Thromb. And Vasc. Biol.* 15(5):571-582.

15. Park, L., et al. (1998) Suppression of accelerated diabetic atherosclerosis by soluble Receptor for AGE (sRAGE). *Nature Medicine*, 4:1025-1031.

16. Park, L., et al. (1997). A murine model of accelerated diabetic atherosclerosis: suppression by soluble receptor for advanced glycation endproducts. Circulation Supplement. Abstract 3079

17. Ritthaler, et al. (1995) Expression of receptors for advanced

glycation end products in peripheral occulsive vascular disease. Am. J. Path. 146:688-694. **(Exhibit 5)**

18. Schmidt, A. M. et al. (1993) Regulation of human mononuclear phagocyte migration by cell surface-binding proteins for advanced glycation end products. *J. Clin. Invest.* 92:2155-2168.

19. Schmidt, A. M., et al. (1997) The V-Domain of Receptor for Advanced Glycation Endproducts (RAGE) mediates binding of AGEs: a novel target for therapy of diabetes. *Circulation Supplement*, 96:194: 1-37.

20. Schmidt, A-M, et al. (1994) Cellular receptors for advanced glycation end products. *Arterioscler. Thromb.*, 14:1521-1528.

21. Schmidt, A. M., et al (1995) The Dark Side of Glucose (News and Views). *Nature Medicine*, 1:1002-1004.

22. Schmidt, A-M, et al. (1994) Receptor for advanced glycation endproducts (AGEs) has a central role in vessel wall interactions and gene activation in response to circulating AGE proteins. *Proc. Natl. Acad. Sci. (USA)*, 91:8807-8811.

23. Schmidt A-M, Yan S-D, Wautier J-L, Stern DM. (1999) Activation of RAGE: a mechanism for chronic dysfunction in diabetic vasculopathy and atherosclerosis. *Circ Res.* 84:489-497. **(Exhibit 6)**

24. Stern et al.,PCT International Publication No. WO 97/26913, published July 31, 1997, PCT International Application No. PCT/US97/00857.

25. Stern, D., AM Schmidt and Jun Wu - PCT International Publication No. WO/98/22138 Published May 28, 1998, PCT International Application No. PCT/US97/21197 filed November 12, 1997 A Method For Treating Symptoms Of Diabetes In A Subject. **(Exhibit 7)**

26. Ulrich, et al., U.S. Patent No. 5,688,653, filing date November 18, 1997.

27. Vlassara et al., U.S. Patent No. 5,585,344, filing date June 27, 1996.

28. Vlassara, H., et al. (1995) Identification of Galectin-3 as a high affinity binding protein for Advanced Glycation Endproducts (AGE): a new member of the AGE-Receptor complex. *Molecular Medicine*, 1:634-646.

29. Vlassara, H., et al. (1994). Pathogenic effects of advanced glycosylation: biochemical, biologic, and clinical implications for diabetes and aging. Lab. Invest. 70: 138-151.

30. Wautier, J. L., et al. (1996) Receptor-mediated endothelial dysfunction in diabetic vasculopathy: sRAGE blocks hyperpermeability in diabetic rats. *J. Clin. Invest.*, 97

(1):238-243.

31. Wautier, J.-L., et al. (1996). Interaction of diabetic erythrocytes bearing advanced glycation endproducts with the endothelial receptor AGE induces generation of reactive oxygen intermediates and cellular dysfunction. Circulation Supplement 94(8):4139.

32. Yan, S-D., et al. (1994) Enhanced cellular oxidant stress by the interaction of advanced glycation endproducts with their receptors/binding proteins. *J. Biol. Chem.*, 269:9889-9897.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorney invites the Examiner to telephone him at the number provided below.

No fee is deemed necessary in connection with the filing of this Communication. However, if any fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

Respectfully submitted,

I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231.

3/4/02
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